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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,362

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Julian Kroin

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6023

25885

7590

10/02/2006

ELI LILLY & COMPANY

PATENT DIVISION

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EXAMINER

BALLS, ROBERT J

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/797,362

Applicant(s)

KROIN ET AL.

Examiner

R. James Balls

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,19,59,66 and 72-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,19,59,66 and 72-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1, 4, 19, 59, 66, and 72-79 are pending.

#### *Priority*

2. This application is a divisional application of application Serial No.10/130,800 filed on May 21, 2002 (Patent No. 6,743,794), which is a 371 of PCT/US00/32443 filed on December 11, 2000, which claims benefit of Provisional Application No. 60/171,373 filed on December 22, 1999 12/22/1999, and claims benefit of Provisional Application No. 60/226,076 filed on August 17, 2000, and claims benefit of Provisional Application No. 60/234,539 filed on September 22, 2000. However, new Claim 77 added in the March 10, 2004 preliminary amendment to the Claims discloses for the first time the intermediate compound: (3-[[5-(2-Chloro-6-fluorophenyl)-3-methyl-3H-imidazole-4-carbonyl]-amino]-cyclohexylmethyl)-carbamic acid benzyle ester. Accordingly, the instant claims are entitled to a priority date of March 10, 2004.

3. Claims 1, 4, 19, 59, 66, and 72-79 are under examination.

#### *Claim Objections*

4. Claims 72 and 77-79 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. The claims are

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dependent upon Claim 1 but are not encompassed by Claim 1 and therefore lack proper antecedent basis. Claim 1 is drawn to compounds wherein the "het" ring is five members but Claims 77-79 have a "het" ring that is six members. Claim 72 appears to be an intermediate, which does not read on Claim 1.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 72 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 72 is drawn to the intermediate: (3-[[5-(2-Chloro-6-fluorophenyl)-3-methyl-3H-imidazole-4-carbonyl]-amino]-cyclohexylmethyl)-carbamic acid benzyle ester, which has no antecedent basis in the specification.

### ***Claim Rejections - 35 USC § 112***

5. Claims 1, 4, 19, 59, 66, and 72-79 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

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make the invention. The Claims are drawn to compounds wherein the "het" ring is five membered and comprises N and a second heteroatom selected from N or S. The specification provides three examples of final product where the "het" ring is a pyrazole, which are claimed in Claims 77-79. No examples of any other "het" rings are provided nor starting materials and/or intermediates disclosed. Starting material sources and procedures for making "het" rings with an additional N or S are not found. Absent starting material sources or a disclosed procedure for making the compounds, the specification lacks enablement for the scope of the claims.

Claim 72 is drawn to an intermediate compound necessary for making the final products of Claims 77-79 but the intermediate compound of Claim 72 was not previously described in the specification.

### ***Conclusion***

6. No Claims are Allowed.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls  
September 26, 2006

  
Celia Chang  
Primary Examiner  
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